K123098

SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional

510(k) Summary

JAN 18 2013

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. **Date:** Sep. 20, 2012
2. **Submitter**
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3. **Primary Contact Person**
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5. **Device**
   A. Trade Name: XGEO GC80
   B. Common Name: Digital Diagnostic X-ray System
   C. Classification Name: System, X-ray, Stationary
   D. Product Code: KPR
6. **Predicate Device**
   A. Manufacturer: General Electric Company
   B. Trade Name: Revolution XR/d Digital Radiographic Imaging System
   C. 510(k) Number: K012389

7. Device Description

The XGEO GC80 digital X-ray imaging system is to be used to take and store image for diagnosis of patients. It consists of the High voltage generator (HVG), Ceiling suspension, Detector, X-ray tube, Patient table, Wall stand, Collimator and etc.

8. Intended Use

The XGEO GC80 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

9. Comparison with predicate device:

The XGEO GC80 described in this 510(k) has the same intended use and similar technical characteristics as the Revolution XR/d of General Electric Company.

Comparison with the predicate device made through the system component items such as detector, generator etc., has been proven to be similar in many ways, but differences in the seven items were found. Specifically, even if the differences of the capacity and size of High Voltage Generator, Ceiling Suspension, Wall stand and Patient table exists, these are considered minor impact on the safety and performance. Also, Collimator, Detector, and Image Process Function in terms of the design and the technology characteristic have differences in the following characteristics:

1) Collimator Rotation: Rotation angles are different but not affect safety. THU head can be rotated to cover ±90. It has not effect on efficiency and safety since the coverage of the angle is the same.

2) Beam light source: Beam light source do not affects safety. LED is more advanced beam light source than Halogen Lamp since it produce low power consumption and good durability. It has not effect on efficiency and safety

3) Resolution of detector: Resolution of detector is different. That affects the image quality but has not an effect on safety. The high contrast resolution of the device has higher than that of the predicate device that is more advantageous.

4) Image Stitching: The XGEO GC80 has the image stitching functionality but not the Revolution XR/d. It has more efficiency since this device can be also used for examinations of long areas of anatomy such as the leg and spine. Also, it has not an

effect on safety since it just produces long length images of subjects by moving a 17 x 17 inch Detector up and down along the Receptor and takes up to 4 images, and transfers these multiple images to the Workstation console and stitch multiple images by image processing on the console.

However, these differences do not have an effect on safety and efficiency compared with the predicate device, Revolution XR/d of General Electric Company.

In summary, the XGEO GC80 does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.
In conclusion, the XGEO GC80 is substantially equivalent to Revolution XR/d of General Electric Company.

10. Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001). All test results were satisfactory.

11. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Samsung Electronics Co., Ltd. concludes that The XGEO GC80 is safe and effective and substantially equivalent to predicate devices as described herein.

12. Samsung Electronics Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 18, 2013

Samsung Electronics Co., Ltd
c/o Mr. Charlie Mack
Principal Engineer
77325 Joyce Way
ECHO OR 97826

Re: K123098
Trade/Device Name: XGEO GC80
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray Systems
Regulatory Class: II
Product Code: KPR
Dated: December 30, 2012
Received: January 15, 2013

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123098

Device Name: XGEO GC80

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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